

# Executive Summary

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All companies everywhere are faced with two problems as they develop their business: Resources (financial, human skills, or assets that cannot be easily acquired) will always be limited, and risk (the possibility of an event with detrimental consequences) will always be involved. Not only is the life science industry no exception, but quite the opposite is true: With most pharmaceutical, biotechnology, and medical device companies operating at the cutting edge where new medical and other scientific insights are converted to marketable products, these companies constantly function in a high-risk business. As far as the resource limitations are concerned, the pharmaceutical industry is clearly feeling a crunch: With patents for top-selling drugs expiring, and too few new drugs gaining approval, there is ample evidence that the entire sector is in the process of restructuring, initially taking a defensive stance to defend earning streams but actually building momentum toward renewed initiatives on a broad front.

In order to get there, measures must be implemented that help companies to stay on top of the changing research and development environment. This report describes and discusses the types of risks that must be faced, the ways that the various risks can be assessed and managed, and how corporate resources can be allocated to meet the goals and to create maximum value according to the corporate strategy.

For a life science company, risk comes in many forms. Failure of a new compound to complete development because of purely medical issues (efficacy and/or safety) is only the most obvious type of risk. Other types include changes in the market environment (for example, because it turns out that another company will be able to launch its competing product earlier, or because the class of drugs to which the candidate drug belongs is burdened with potential side effects); changes of regulatory or reimbursement practices; unforeseen problems with intellectual property that is supposed to protect the drug candidate; failure of execution for a variety of reasons, many of which are associated with human nature;

problems with information technology, including compromised data security; unexpected safety problems emerging after a drug has been launched; and public relations disasters, which can result from almost any of the above. Not all of these risks can be avoided, but many can be mitigated and managed if they are addressed proactively.

Intimately associated with the risk issue is the valuation of projects and portfolios. This report outlines the major approaches along which objective and quantitative valuation of drug development can be attempted, although a detailed discussion is far beyond its scope.

Resource allocation and planning also have aspects that are specific to the life science industry. Many resource-intensive activities of a pharmaceutical company are mandated by regulatory authorities and are therefore all but “untouchable,” while other corporate operations that are not regulated frequently show extensive potential for streamlining. “Lean” and “Six Sigma” are catchwords that describe resource-saving process optimization and quality control approaches that have found a firm place in our industry. Managing laboratory equipment (including service contracts) and inventories is another issue that can result in remarkable savings.

On the life science company’s strategic level, resource allocation management can largely be equaled with portfolio management, the hub function that assembles individual drug development projects into an integrated larger whole that gives a form and a master plan to the company’s development strategy and coordinates these projects in such a way that optimal value is created. Advanced software suites are available that help managers handle the huge corporate data streams on the operational plane (enterprise resource management [ERP]) and on the level of business intelligence, where internal data warehouses are analyzed to provide key figures and profiles that help in decision-making. “Help” is the operative term, for no “strategic” software available today can do more than assist management’s judgment and governance.

Finally, this report provides case studies that illustrate how pharmaceutical companies of various sizes and types have addressed their portfolio management issues. No magic formula emerges from this discussion—and there can never be one—for the simple reason that no two companies are identical, and there is no single optimal

way to manage a company. In the recently published bestseller, *The Halo Effect and the Eight Other Business Delusions* (The Free Press, 2007), Phil Rosenzweig illustrates the fundamental cognitive bias that leads managers—and even management theoreticians—to perceive a particular business strategy as “correct” as long as the observed company shows evidence of success, while the very same strategy is faulted with equal conviction once the vicissitudes of business turn against that same company. The issue is quite similar with a drug development portfolio: Management must walk the line of balance that separates consequent policy from inflexibility.

The first of the two most consequential take-home messages that we want to convey is that good portfolio management practice is not a matter of establishing a discussion culture, but one of implementing sound, data-driven, and transparent decision processes. The second message is that, even as seen in the light of the previous insight, portfolios and their constituent projects are ultimately managed by people, not by functions. Objections to portfolio management, or attempts to push it in a certain direction, frequently arise from less rational elements in the personalities of the acting people, even if they are driven by the best intentions. A good portfolio manager will be aware of this and make use of these human features instead of attempting their suppression.

Management of risks, resources, and portfolios is a key challenge for any life science company that wants to survive the difficult times through which the industry is now passing. The restructured pharma industry that will come roaring back within the next few years will consist of leaner and more effective companies, and certainly all of these survivors will have learned how to manage their risks and resources strategically.

